EXHIBIT 76

Forced air warming device failure resulting in smoke and soot on a surgical patient [A-732-0069-00191]

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Introduction

Forced air warming (FAW) devices are used in the operating room to maintain normothermia. Proper use involves connecting the hose of the warming unit to a disposable blanket with a perforation pattern that evenly distributes heat across the patient's body (Fig 1). We present the case of a FAW device that malfunctioned after it became wet, depositing black soot on the patient.

Figure 1: Forced air warming unit attached via hose to disposable blanket

Case Report

A 67 year old patient with lung cancer presented for robotic-assisted left upper lobectomy. The patient was taken to the operating room, ASA monitors were applied, general anesthesia was induced, and the airway was secured. After arterial and peripheral line placement, the patient was positioned in the right lateral decubitus position. A FAW blanket was applied to the patient's lower body, and the heating device was set to 43° C. The foley temperature was initially 35.7° C, decreased to 35.0° C, and increased to 35.8° C by the end of the case. While closing the chest, the line isolation monitor alarmed and was investigated. A few minutes later smoke was noticed in the field, and the drapes were removed to identify the source. No flames were seen, and no obvious source of smoke was identified. Then, black punctate spots were noted on the sheets and the patient's lower extremities (Fig 2). Upon investigation, the black spots were soot deposited on the patient in the pattern of the perforation holes of the FAW blanket (Fig 3). The soot was wiped off the patient, and there was no injury to the patient. The blanket itself was dry, but the warming unit was sitting in irrigation that spilled from the surgical field.

Figure 2: Soot marks on sheets SCDs and patient lower extremities

Figure 3: Perforation holes of disposable blanket with black soot

Discussion

The Food and Drug Administration and Anesthesia Patient Safety Foundation discourage "hosing" (1-2), defined as the misuse of FAW devices by applying the hose directly to the patient or to a non-inflatable blanket. This misuse has resulted in various reports of first to third degree burns (3-5), including a reported amputation due to muscle necrosis. In our case, however, the FAW device was properly utilized with the hose attached to an inflatable blanket. Our biomedical service evaluated this incident and device and concluded that the air-intake on the bottom of the unit entrained irrigation into the device, causing a short circuit within the unit. This electrical short created smoke inside the device, which was then blown out through the hose and deposited as soot through the perforation holes in the blanket. The unit was removed from service and returned to the manufacturer. This is a case of a near-miss that could easily have resulted in an OR fire.

References

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